

## **REMARKS**

In the Office Action dated August 19, 2008, the Examiner rejected claims 1, 2, and 9 under 35 U.S.C. § 112 (2<sup>nd</sup> paragraph) as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention. The Examiner also reiterated his rejection of claims 1-3, 5-6, 8-9, 14-21, and 28-29 under 35 U.S.C. § 112 (1<sup>st</sup> paragraph) as failing to comply with the enablement requirement.

In response to these rejections, the Applicants present the following arguments.

### **Telephone Interview**

The Applicants thank the Examiner for the courtesies extended to the Applicants' representative during a telephone interview on November 17, 2008 to discuss whether the attached affidavits are sufficient to meet the requirements associated with the Budapest Treaty.

### **35 U.S.C. § 112 (2<sup>nd</sup> paragraph)**

In the August 19, 2008 Office Action, the Examiner rejected claims 1 and 2 under 35 U.S.C. § 112 (2<sup>nd</sup> paragraph) as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention. Specifically, the Examiner stated that the dependant claim 2 appears inconsistent with independent base claim 1. In response, the Applicants cancel claim 2, which avoids any inconsistency.

The Examiner also rejected claim 9 under 35 U.S.C. § 112 (2<sup>nd</sup> paragraph) as being incomplete for omitting essential structural cooperative relationships of elements, which the Examiner stated amounts to a gap between the necessary structural connections. The Examiner specified that the omitted structural cooperative relationships are the recitation in lines 15-16, which the Examiner stated are not properly connected to the claim's preamble in lines 1-2. The Applicants have amended claim 9 to respond to this rejection. As amended, claim 9 is limited to the specific vector under CECT; for this reason, it is not necessary to specify all of the structural features of the vector, as these structural features are inherent to the deposited vector. In addition, the amendment renders the language of claim 9 clearer in its definition of homologous recombination vectors.

For these reasons, the Applicants respectfully request that these rejections of claims 1 and 9 be withdrawn.

### **35 U.S.C. § 112 (1<sup>st</sup> paragraph)**

In the August 19, 2008 Office Action, the Examiner rejected claims 1-3, 5-6, 8-9, 14-21, and 28-29 under 35 U.S.C. § 112 (1<sup>st</sup> paragraph). The Examiner stated that the claims contain subject matter not described in the specification in a way that enables one skilled in the art to make and use the invention. The Examiner stated that the Applicants' reference to the deposit of the vector identified as pHR53TK used for generating a disruption in a gene of an endogenous Sigma-1 receptor of mouse in the claims and the specification is insufficient assurance that all the conditions of 37 C.F.R. part 1.801-1.809 have been met. The Examiner then stated that if the deposit was made under the Budapest Treaty, the Applicants must file an affidavit or declaration (or a statement by an attorney of record over his or her signature and registration number) stating (a) that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, (b) that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application, and (c) that the deposit will be replaced if viable samples cannot be dispensed by the depository.

The Applicants respond to this rejection by providing a copy of an affidavit from Mr. Eduard Valentí, who represents the Laboratorios del Dr. Esteve, the application's sole assignee. In this affidavit, Mr. Valentí acknowledges all points (a) to (c), recited above. Thus, this affidavit sufficiently meets the Budapest Treaty's requirements, and therefore this rejection should be withdrawn.

The Examiner also notes that the Applicants must amend the specification to give the date of the deposit as well as the complete name and address of the depository. In response to this statement, the Applicants note that paragraph [151] of the publication of the specification clearly specifies the accession number for the deposit (CECT 5737), the date of the deposit (Oct. 4, 2002), the name and address of the depository (Colección Española de Cultivos Tipo CECT Burjassot, Valencia, Spain), and a description of the deposited material sufficient to specifically identify it and to permit examination (the specification states that the pHR53TK vector whose specific features are fully described in the whole of the specification is deposited inside an Escherichia coli top 10° F culture). Thus, the specification as it is currently written contains the information the Examiner has stated is required, and therefore this rejection should be withdrawn.

The Examiner then notes in his Response to Applicants' Arguments of 03/31/2008 that although the Applicants' biological deposit form meets the Budapest Treaty, the form indicates a date of January 5, 2006, which is after the date of filing. The Examiner indicated that the Applicants may provide a declaration filed under 37 C.F.R. part 1.132 to construct a chain of custody, and that the declaration should (a) identify the deposited material by its depository accession number, (b) establish that the deposited material is the same as that described in the specification, and (c) establish that the deposited material was in the Applicants' possession at the time of filing.

In order to comply with these requirements, the Applicants have provided an affidavit from an inventor, Dr. Lluís Montoliu José. In this affidavit, Dr. Montoliu acknowledges each of points (a) to (c), recited above. Thus, this affidavit sufficiently meets the Budapest Treaty's requirements, and therefore this rejection should be withdrawn.

For these reasons, the Applicants respectfully request that this rejection of claims 1-3, 5-6, 8-9, 14-21, and 28-29 be withdrawn.

## **Conclusion**

In view of the amendments to the claims and the remarks set forth above, the Applicants respectfully submit that the present invention is in condition for allowance.

The Applicants authorize any overcharges to be charged to, and any credits to be applied to deposit account no. 50-1519.

Respectfully submitted,

/Luke T. Shannon/

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CONSULAR DIVISION

REINO DE ESPAÑA  
EMBAJADA DE LOS ESTADOS  
UNIDOS DE AMÉRICA  
DIVISIÓN CONSULAR

AFFIDAVIT

I, Lluís Montoliu José, of legal age, of profession chemist and resident to this effect of the city of Barcelona, Spain, do hereby declare and state that:

- 1) I am an inventor of the United States patent application no. 10/731,379, titled "Non-human Mutant Mammals Deficient in Sigma Receptors and Their Application", filed on December 9<sup>th</sup>, 2003.
- 2) The deposit material referred to in the patent application above has been accepted by an international depository authority, the Colección Española de Cultivos Tipo (CECT), as deposit number CECT 5737 on October 4<sup>th</sup>, 2002.
- 3) The deposited material is the same as the described in specification of the patent application above.
- 4) The deposit material was in my possession at the moment of filing the patent application referred to before.

Signed in Madrid, Spain on September \_\_, 2008.

\_\_\_\_\_  
Lluís Montoliu José

DECLARACIÓN JURADA

Yo, Lluís Montoliu José, mayor de edad, con D.N.I. 43498444Q de profesión químico y residente para estos efectos de la ciudad de Madrid, España, declaro y afirmo que:

- 1) Soy inventor de la solicitud de patente estadounidense número 10/731,379, titulada "Non-human Mutant Mammals Deficient in Sigma Receptors and Their Application", presentada el 9 de diciembre de 2003.
- 2) El material de depósito referido en la antedicha solicitud de patente, ha sido aceptado por una autoridad depositaria internacional, la Colección Española de Cultivos Tipo (CECT), bajo el número de depósito CECT 5737 el 4 de octubre de 2002.
- 3) El material depositado es el mismo descrito en la descripción de la solicitud de patente arriba indicada.
- 4) El material de depósito estaba en mi posesión al momento de presentar la solicitud de patente antes referida.

Dado en Madrid, España, el 30 de Septiembre de 2008.

\_\_\_\_\_  
Lluís Montoliu José

DNI: 043498444Q




Witness Domingo Represa Sánchez  
CSIC-IPR Department  
Domingo Represa

## AFFIDAVIT

I, Eduard Valentí, of legal age, of profession chemist and resident of the city of Barcelona, Spain, in representation of Laboratorios del Dr. Esteve, S.A. ("Esteve"), do hereby declare and state that:

- 1) Esteve is the sole assignee of the United States patent application no. 10/731,379, titled "Non-human Mutant Mammals Deficient in Sigma Receptors and Their Application, filed on December 9<sup>th</sup>, 2003.
- 2) The deposit material referred to in the patent application above has been accepted by an international depository authority under the Budapest Treaty, the Colección Española de Cultivos Tipo (CECT), as deposit number CECT 5737 on October 4<sup>th</sup>, 2002.
- 3) All restriction upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application.
- 4) The deposit will be replaced if viable samples cannot be dispensed by the depository.

Signed in Barcelona, Spain on September 29, 2008.



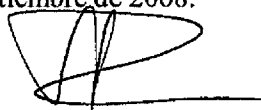
Dr. Eduard Valentí  
Attorney-in-fact  
LABORATORIOS  
DEL DR. ESTEVE, S.A.

## DECLARACIÓN JURADA

Yo, Eduard Valentí, mayor de edad, de profesión químico y residente de la ciudad de Barcelona, España, en representación de Laboratorios del Dr. Esteve, S.A. ("Esteve"), declaro y afirmo que:

- 1) Esteve es el único cesionario de la solicitud de patente estadounidense número 10/731,379, titulada "Non-human Mutant Mammals Deficient in Sigma Receptors and Their Application, presentada el 9 de diciembre de 2003.
- 2) El material de depósito referido en la antedicha solicitud de patente ha sido aceptado por una autoridad depositaria internacional bajo el Tratado de Budapest, la Colección Española de Cultivos Tipo (CECT), bajo el número de depósito CECT 5737 el 4 de octubre de 2002.
- 3) Toda restricción de acceso del público al material depositado será retirada irrevocablemente al concederse la patente objeto de esta solicitud.
- 4) El material de depósito será reemplazado si la entidad depositaria no puede entregar muestras viables.

Dado en Barcelona, España, el 29 de septiembre de 2008.



Dr. Eduard Valentí  
Apoderado  
LABORATORIOS  
DEL DR. ESTEVE, S.A.

LEGITI-

-MACIÓN-

YO, TOMÁS GIMÉNEZ DUART, NOTARIO DEL IL.LUSTRE COL.LEGI  
DE NOTARIS DE CATALUNYA, Y POR OPOSICIÓN NOTARIO DE  
BARCELONA, \_\_\_\_\_

DOY FE: De que considero legítima la firma que antecede de DON  
EDUARD VALENTÍ VALL por haberla contrastado con otras originales que  
figuran en documentos obrantes en mi poder. \_\_\_\_\_

En Barcelona, a 23 de septiembre de 2008. \_\_\_\_\_

